K052556

JAN 9 2006

CARD GUARD

CG-7000DX-BT ECG Recorder/Transmitter 510(k) Summary of Safety and Effectiveness

1. Definition and Intended Use

The CG-7000DX-BT ECG Recorder/Transmitter is a 12 Lead ambulatory electrocardiograph capable of recording and transmitting up to 40 standard ECGs for the purpose of cardiac monitoring and diagnosis. The device incorporates a recording and transmitting circuitry, graphic LCD, a package of firmware tools. The BT module (Tiden-Yuden Ltd.) conveys data to a remote hand held receiving device/PC or laser/Ink-jet printer.

The CG-7000DX-BT is intended for use by a medical professional:

a. The ECG is recorded and transmitted to a remote receiving station for consultation with a cardiologist.

b. The ECG is recorded and transferred to a remote hand held device/PC/printer for viewing and processing.

CG-7000DX-BT is classified as Class II medical device.

2. Referenced Standards

No performance standards have been developed under Section 514 of the Federal Food, Drug and Cosmetic Art for telephone ECG transmitter devices. The CG-7000DX-BT Recorder/Transmitter meets the requirements of the following standards:

(1) ANSI/AAMI EC38, "Ambulatory Electrocardiographs" 1994

(2) ANSI/AAMI EC13 Cardiac Monitors, Heart Rate Metersand Alarms, 2nd edition 1992

(3) ANSI/AAMI EC11 Diagnostic Electrocardiographic Devices, 2nd edition 1991

(4) IEC 601-1- 4: 1996 Medical Electrical Equipment (safety).

3. Features and Functions

1. Graphic display for ECG representation and device control
2. One screen shows 1,52 sec lead length. For viewing full leads scrolling is used
3. Device features a keypad with 17 keys for device control and data input
4. Device is energized by pressing power on/off key
5. Device records 12-leads ECG simultaneously and stores up to 40 ECG
6. Lead duration is menu selectable: 4, 8, 12, 16, and 20 seconds
7. All records include a mandatory minimum 12 seconds arrhythmia trace
8. Recorded ECG and data are transmitted via BT class II module (Tiden-Yuden Ltd.) to a remote hand held receiving device/PC or laser/Ink-jet printer.
9. Low battery detection
10. BIT mode is provided for the device self-test
11. Accurate pacemaker artifact detection and marking
12. Patient Cable with a cable-connector, a molded fanout shell and 10 lead wires

4. Substantial Equivalence

CG-7000DX-BT is substantially equivalent to Card Guard CG-7000DX, legally marketed under 510(k) premarket clearance k993799 and resembles PMP[4] SelfCheck™ ECG k042254 in the use of the Bluetooth method and protocol.

CG-7000DX-BT and CG-7000DX have the same main principles of operation and technical specifications. The differences between the devices are intended to improve the effectiveness for its intended use, and are shown to have no adverse effect on safety and efficacy.

CG-7000DX-BT and CG-7000DX, have the following characteristics in common:

- Similar intended use, and
- Similar principles of operation, features and technological characteristics.

5. Material differences

The most important innovation in CG-7000DX-BT is its new capability to transmit data via Bluetooth (instead of the Universal IR/Acoustic Adapter) to a remote hand held receiving device and printer (in addition to the receiving station, and a local PC).

Bluetooth is an open standard for short-range transmission of data that supports point-to-point and multipoint applications.

6. Conclusions

CG-7000DX-BT ECG Recorder/Transmitter, constitutes a safe and reliable means for recording and transmitting standard ECG for the purpose of cardiac condition monitoring and diagnosis. Its material composition and of operation present no adverse health effect or safety risks to patients when used as intended.

The device is as safe, as effective and performs as well as or better than its cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 9 2006

Card Guard Scientific Survival, Ltd.
c/o Mr. Alex Gonorovsky
Manager, Regulatory Affairs
2 Pekeris St.
Rehovot
ISRAEL

Re: K052556
Trade Name: CG-7000DX-BT ECG Recorder/Transmitter
Regulation Number: 21 CFR 870.2920
Regulation Name: Transmitters and receivers, Electrocardiograph, Telephone
Regulatory Class: Class II (two)
Product Code: DXH
Dated: December 19, 2005
Received: December 23, 2005

Dear Mr. Gonorovsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052556

Device Name: CG-7000DX-BT ECG Recorder/Transmitter

Indications for Use:

12-Lead electrocardiograph capable of recording and transmitting up to 40 standard ECGs for the purpose of cardiac monitoring and diagnosis, incorporates recording/ transmitting circuitry, graphic LCD, a package of firmware tools and is intended for use by a medical professional:

a. The ECG is recorded and transmitted to a remote receiving station for consultation with a cardiologist.

b. The ECG is recorded and transferred to a remote hand held device/PC/printer for viewing and processing.

Prescription Use [X] _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

/ision Sign-Off)
Ision of Cardiovascular Devices
)(k) Number K052556

(Posted November 13, 2003)